

SEP 11 2001

K011403

## 510(k) Summary

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*Submitted on behalf of:*

**Company Name:** Orthogen Corporation  
**Address:** 530 Morris Avenue, Ste 204  
Springfield, NJ 07081  
**Telephone:** 973-467-2404  
**Fax:** 973-467-1218

**by:** President, Paladin Medical, Inc.  
PO Box 560  
Stillwater, MN 55082  
**Telephone:** 715-549-6035  
**Fax:** 715-549-5380

**CONTACT PERSON:** Elaine Duncan, M.S.M.E., RAC

**DATE PREPARED:** May 3, 2001

**TRADE NAME:** SURGIPLASTER™ Calcium Sulfate Hemihydrate

**COMMON NAME:** Bone filling augmentation material

**SUBSTANTIALLY EQUIVALENT TO:**

CAPSET Calcium Sulfate Bone Substitute K 955096 and Fortoss- CEMA K993238

**DESCRIPTION of the DEVICE:** SURGIPLASTER™ Calcium Sulfate Hemihydrate, supplied by CLASSimplant, s.r.l., distributed by Orthogen Corporation, is a medical grade calcium sulfate hemihydrate powder. SURGIPLASTER is designed to set-up in vivo and may be used either alone or mixed with DFDBA (demineralized freeze-dried bone allograft) or autogenous bone in bone regenerative procedures. It is mixed with small amounts of regular setting solution to produce a putty-like paste and it is applied on bone defects in overlapping layers. Each layer is then compressed with a small square of sterile gauze. The last layer is set using a small square of sterile gauze soaked in the fast setting solution. With time, the resorbing, set SURGIPLASTER dissolves and recedes leaving behind bioactive calcium phosphate deposits that have been found to stimulate bone in-growth.

**INDICATIONS FOR USE:**

SURGIPLASTER™ Calcium Sulfate Hemihydrate is indicated for use in the following ways; by itself in bone regenerative techniques; mixed with other suitable bone filling agents to prevent particle migration in an osseous defect; and, to provide a resorbable barrier over other bone graft material

**SUMMARY of TESTING:**

Orthogen Corporation has 1) tested the chemical composition of SURGIPLASTER™ Calcium Sulfate Hemihydrate by an independent laboratory to a recognized test method (USP NSF 18) and reported the results in this submission; and, 2) has provided extensive literature articles documenting the use of calcium sulfate as a bone augmentation material, including an extensive literature reference. Therefore this material has been qualified as biocompatible and safe for its intended use.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Orthogen Corporation  
C/O Ms. Elaine Duncan  
Paladin Medical, Incorporated  
P.O. Box 560  
Stillwater, Minnesota 55082

Re: K011403

Trade/Device Name: Surgiplaster Calcium Sulfate Hemihydrate  
Regulation Number: 872.3640  
Regulation Name: Bone Filing Augmentation Material  
Regulatory Class: Unclassified  
Product Code: LYC  
Dated: August 3, 2001  
Received: August 6, 2001

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

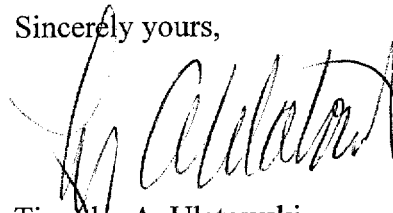
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Timothy A. Ulatowski  
Director

Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known) \_\_\_\_\_

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Device Name: SURGIPLASTER™ Calcium Sulfate Hemihydrate

**Indications for Use:**

SURGIPLASTER™ Calcium Sulfate Hemihydrate is indicated for use in the following ways:

- by itself in bone regenerative techniques
- mixed with other suitable bone filling agents to prevent particle migration in an osseous defect
- to provide a resorbable barrier over other bone graft material

**(Please Do Not Write Below This Line-Continue On Another Page If Needed)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)

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(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K011403